

11-16-05

IPW



PATENT
Customer No. 22,852
Attorney Docket No. 07579.0015-01000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Graham E. KELLY et al.) Group Art Unit: 1614
Application No.: 10/600,004) Examiner: Cybille DELACROIX-MUIRHEID
Filed: June 18, 2003)
For: CARDIOVASCULAR AND) Confirmation No.: 6037
BONE TREATMENT USING)
ISOFLAVONES)

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

FIFTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
RESUBMITTING REFERENCES PREVIOUSLY SUBMITTED AND/OR IDENTIFIED
UNDER 37 C.F.R. § 1.97

Pursuant to 37 C.F.R. §§ 1.56 and 1.97, Applicants bring to the attention of the Examiner the documents on the attached listing. This Information Disclosure Statement (IDS) is being filed after a Final Action and accordingly is accompanied by the fee set forth under 37 C.F.R. § 1.97(d). Specifically, Applicants request the Office to debit the fee of \$180.00 as specified under § 1.17(p) from Deposit Account No. 06-0916. However, this IDS resubmits references previously submitted and/or identified and, accordingly Applicants cannot make the statements under 37 C.F.R. § 1.97(e). Thus, Applicants ask that the Examiner waive that aspect of the rule and consider these resubmitted documents. Applicants also respectfully request that the

Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

Copies of the listed foreign and non-patent literature documents are attached. A copy of the listed U.S. patent is not enclosed, pursuant to current Office practice.

Every document in this submission (except for the U.S. patent) was previously submitted in prior Information Disclosure Statements and many were considered by the Examiner in the parent case, Application No. 09/914,315, now abandoned. However, the Examiner did not initial that these particular references were considered. Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

U.S. Appl. No. 09/602,191: This commonly-assigned, pending application (corresponding to our Docket No. 07579.0001-00000) was listed on the Information Disclosure Statement filed on September 11, 2003, but it is possible that a paper copy was not provided. A copy of the pending claims is attached. The specification is available as US 5,830,877, which was previously cited in the Information Disclosure Statement filed on September 11, 2003.

DE 44 32 947 A1: This German language patent was not complete when submitted on December 13, 2004 (with the Intl. Search Report in which it was cited). A complete copy of the patent is resubmitted herewith with an English language Abstract attached.

EP 0 906 761 A2: This patent was listed on the Information Disclosure Statement filed on December 13, 2004, but it is possible that a paper copy was not enclosed. The Examiner previously considered this reference on December 15, 2002, in the parent case, Application No. 09/914,035, now abandoned. In addition, it was cited in the corresponding PCT Search Report

as an "X" reference, and the corresponding EP Examination Report (copies enclosed and cited on the attached PTO/SB/08). A copy of the patent is submitted herewith.

JP 50-035393: This Japanese language patent was submitted on December 13, 2004 without an English abstract. A copy is resubmitted with an English language Abstract attached to the front of the patent. In addition, it is believed this patent is also published as US 3,974,184, as referenced on the attached PTO/SB/08.

WO 02/074307 A1: This patent was submitted on January 6, 2004 with pages missing. A complete copy is resubmitted herewith.

Anderson et al.: This document was listed on the Information Disclosure Statement filed on December 13, 2004, and it is believed a complete copy of the reference was included in the submission. In addition, the Examiner previously considered this reference on December 15, 2002, in the parent case, Application No. 09/914,035, now abandoned. A complete copy is resubmitted herewith.

Dubey et al.: This document was listed on the Information Disclosure Statement filed on December 13, 2004, but it is possible that a paper copy was not enclosed. The Examiner previously considered this reference on December 15, 2002, in the parent case, Application No. 09/914,035, now abandoned. In addition, it was cited in the corresponding PCT Search Report as an "X" reference. A complete copy is submitted herewith.

Fanti et al.: This document was listed on the Information Disclosure Statement filed on December 13, 2004, but it is possible that a paper copy was not enclosed. The Examiner previously considered this reference on December 15, 2002, in the parent case, Application No. 09/914,035, now abandoned. A complete copy is submitted herewith.

Gennaro, A.R.: This document was listed on the Information Disclosure Statement filed on December 13, 2004, but it is possible that a paper copy was not enclosed. The Examiner previously considered this reference on December 15, 2002, in the parent case, Application No. 09/914,035, now abandoned. A complete copy is submitted herewith.

Goodman et al.: This document was listed on the Information Disclosure Statement filed on December 13, 2004, but it is possible that a paper copy was not enclosed. The Examiner previously considered this reference on December 15, 2002, in the parent case, Application No. 09/914,035, now abandoned. A complete copy is submitted herewith.

Gordon et al.: This document was listed on the Information Disclosure Statement filed on December 13, 2004, but it is possible that a paper copy was not enclosed. The Examiner previously considered this reference on December 15, 2002, in the parent case, Application No. 09/914,035, now abandoned. A complete copy is submitted herewith.

Grunert, E. et al.: This German language document was listed on the Information Disclosure Statement filed on December 13, 2004. Another copy is submitted herewith. An abstract in English is located on the last page of the article.

Hodgson, J. et al.: This document was listed on the Information Disclosure Statement filed on December 13, 2004, but it is possible that a paper copy was not enclosed. The Examiner previously considered this reference on December 15, 2002, in the parent case, Application No. 09/914,035, now abandoned. A complete copy is submitted herewith.

Mazur et al.: This document was listed on the Information Disclosure Statement filed on December 13, 2004, but it is possible that a paper copy was not enclosed. The Examiner previously considered this reference on December 15, 2002, in the parent case, Application No.

09/914,035, now abandoned. In addition, it was cited in the corresponding PCT Search Report as an "A" reference. A complete copy is submitted herewith.

Nestel, P., et al., *J. Clin. Endocrinol. Metab.* 84: This document was listed on the Information Disclosure Statement filed on December 13, 2004, but it is possible that a paper copy was not enclosed. The Examiner previously considered this reference on December 15, 2002, in the parent case, Application No. 09/914,035, now abandoned. In addition, it was cited in the corresponding PCT Search Report as an "X" reference. A complete copy is submitted herewith.

Nestel, P. et al., *Arterioscler. Thromb. Vascular Biol.*: This document was listed on the Information Disclosure Statement filed on December 13, 2004, but it is possible that a paper copy was not enclosed. The Examiner previously considered this reference on December 15, 2002, in the parent case, Application No. 09/914,035, now abandoned. A complete copy is submitted herewith.

Panchagnula, R. et al.: This document was listed on the Information Disclosure Statement filed on December 13, 2004, but it is possible that a paper copy was not enclosed. The Examiner previously considered this reference on December 15, 2002, in the parent case, Application No. 09/914,035, now abandoned. A complete copy is submitted herewith.

Potter, S. et al.: This document was listed on the Information Disclosure Statement filed on December 13, 2004, but it is possible that a paper copy was not enclosed. The Examiner previously considered this reference on December 15, 2002, in the parent case, Application No. 09/914,035, now abandoned. A complete copy is submitted herewith.

Samman, S. et al.: This document was listed on the Information Disclosure Statement filed on December 13, 2004, but it is possible that a paper copy was not enclosed. The Examiner

previously considered this reference on December 15, 2002, in the parent case, Application No. 09/914,035, now abandoned. A complete copy is submitted herewith.

Schulz, G.: This German language document was listed on the Information Disclosure Statement filed on December 13, 2004. A complete copy is resubmitted herewith with a certified English translation.

Sharma, R.D.: This document was listed on the Information Disclosure Statement filed on December 13, 2004, but it is possible that a paper copy was not enclosed. The Examiner previously considered this reference on December 15, 2002, in the parent case, Application No. 09/914,035, now abandoned. In addition, this document was cited in the corresponding PCT Search Report as an “X” reference. A complete copy is submitted herewith.

Walz, E.: This German language document was listed on the Information Disclosure Statement filed on December 13, 2004, without any English language translation or statement of relevance. A complete copy is resubmitted with an English abstract.

Wilcox, G. et al.: This document was listed on the Information Disclosure Statement filed on December 13, 2004, but it is possible that a paper copy was not enclosed. A complete copy is submitted herewith.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute “prior art.” If the Examiner applies any of the documents as prior art against any claims in the application and Applicants determine that the cited documents do not constitute “prior art” under United States law, Applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: November 14, 2005

By: Elisabeth Barek
Elisabeth Jaffe Barek
Reg. No. 46,797

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

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Complete if Known

Application Number	10/600,004
Filing Date	June 18, 2003
First Named Inventor	Kelly
Art Unit	1614
Examiner Name	Delacroix-Muirheid, Cybille
Attorney Docket Number	07579.0015-01000

U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS

Note: Submission of copies of U.S. Patents and published U.S. Patent Applications is not required.

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation ²
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
		DE 44 32 947 A1	03-21-1996	New Standard GmbH		Abstract
		EP 0 906 761 A2	04-07-1999	Archer Daniels Midland Co.		
		JP 50-0035393	04-04-1975	Zaidan Hojin Biseibutsu Kagaku Kenkyu Kai		Abstract
		WO 02/074307 A1	09-26-2002	Novogen Research Pty. Ltd.		

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation
		Anderson, J.J.B. et al., "Biphasic Effects of Genistein on Bone Tissue in the Ovariectomized, Lactating Rat Model," <i>P.S.E.B.M.</i> 217:345-350 (1998).	
		Dubey, R.K. et al. "Phytoestrogens Inhibit Growth and MAP Kinase Activity in Human Aortic Smooth Muscle Cells," <i>Hypertension</i> 33(part II):177-182 (1999).	
		Fanti, P. et al. "The Phytoestrogen Genistein Reduces Bone Loss in Short-Term Ovariectomized Rats," <i>Osteoporosis Int.</i> 8:274-281 (1998).	
		Gennaro, A.R. (Ed.), <i>Remington's Pharmaceutical Sciences</i> , 17 th Edition, Mack Printing Co., Easton, PA, Table of Contents, 4 pages (1985).	
		<u>Goodman and Gilman's The Pharmacological Basis of Therapeutics</u> , 7 th Edition, Macmillan Publishing Co., New York, Table of Contents, 8 pages (1985).	

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet	2	of	2	Attorney Docket Number	07579.0015-01000
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Complete if Known

Application Number	10/600,004
Filing Date	June 18, 2003
First Named Inventor	Kelly
Art Unit	1614
Examiner Name	Delacroix-Muirheid, Cybille

NON PATENT LITERATURE DOCUMENTS

	Gordon, D.J. et al. "High-Density Lipoprotein Cholesterol and Cardiovascular Disease, Four Prospective American Studies," <i>Circulation</i> 79(1):8-15 (1989).	
	Grunert, E. and Woelke, G., "Isoflavone in einigen Weiß- und Rotkleesorten und ihre oestrogene Wirksamkeit bei juvenilen Mäusen," <i>Deutsche Tierärztliche Wochenschrift</i> 74:431-433 (1967). English Abstract on p. 432.	Abstract
	Hodgson, J.M. et al., "Supplementation with isoflavonoid phytoestrogens does not alter serum lipid concentrations: A randomised controlled trial in humans," <i>J. Nutr.</i> 128: 728-732 (1998).	
	Mazur, W. and Adlercreutz, H. et al., "Natural and anthropogenic environmental oestrogens: the scientific basis for risk assessment - Naturally occurring oestrogens in food," <i>Pure & Appl. Chem.</i> 70(9):1759-1776 (1998).	
	Nestel, P.J. et al., "Isoflavones from red clover improve systemic arterial compliance but not plasma lipids in menopausal women," <i>J. Clin. Endocrinol. Metab.</i> 84(3):895-898 (1999).	
	Nestel, P.J. et al., "Soy isoflavones improve systemic arterial compliance but not plasma lipids in menopausal and perimenopausal women," <i>Arterioscler. Thromb. Vasc. Biol.</i> 17:3392-3398 (1997).	
	Panchagnula, R. et al., "Transdermal iontophoresis revisited," <i>Curr. Opin. Chem. Biol.</i> 4(4):468-473 (2000).	
	Potter, S.M. et al., "Soy protein and isoflavones: their effects on blood lipids and bone density in postmenopausal women," <i>Am. J. Clin. Nutr.</i> 68(suppl):1375S-1379S (1998).	
	Samman, S. et al., "The effect of supplementation with isoflavones on plasma lipids and oxidisability of low density lipoprotein in premenopausal women," <i>Atherosclerosis</i> 147:277-283 (1999).	
	Schultz, G., "Isoflavonoglucoside Formononetin-7-glucosid und Biochanin A-7-glucosid in <i>Trifolium pratense</i> L.," <i>Die Naturwissenschaften</i> 52(18):517 (1965). 3 page certified English translation attached.	YES
	Sharma, R.D., "Effect of Various Isoflavones on Lipid Levels in Triton-treated Rats," <i>Atherosclerosis</i> 33:371-375 (1979).	
	Walz, E., "Isoflavon- und Saponin-Glucoside in <i>Soja hispida</i> ," <i>Justus Liebigs Ann. Chem.</i> 489:118-155 (1931). 1 page English abstract attached.	Abstract
	Wilcox, G. et al., "Oestrogenic effects of plant foods in postmenopausal women," <i>British Med. J.</i> 301:905-906 (1990).	
	International Search Report for PCT/AU/00384, mailed on July 13, 2000, 3 pages.	
	European Patent Office Examination Report for EP Appl. No. 00 920 267.2, mailed on July 14, 2005, 4 pages.	
	U.S. Appl. No. 09/602,191, pending claims, 2 pages.	

Examiner Signature		Date Considered	
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.